General

Guideline Title

Evidence-based clinical practice guideline: breast reconstruction with expanders and implants.

Bibliographic Source(s)

American Society of Plastic Surgeons. Evidence-based clinical practice guideline: breast reconstruction with expanders and implants. Arlington Heights (IL): American Society of Plastic Surgeons; 2013 Mar. 23 p. [71 references]

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

Definitions for the levels of evidence (I–V) and the grades of the recommendations (A–D) are provided at the end of the "Major Recommendations" field.

Considerations for Surgical Planning

Patient Education

Recommendation: Patients undergoing mastectomy should be offered a pre-operative referral to a plastic surgeon. The adoption of this approach by practicing surgeons would benefit breast cancer patients nationwide and would result in enhanced patient education of reconstructive options. *Grade: D*

Immediate Versus Delayed Reconstruction

Recommendation: Evidence is varied and conflicting on the association between post-operative complications and the timing of post-mastectomy expander/implant breast reconstruction and is often confounded by the use of radiation. The inconsistent research findings and a lack of definitive evidence should alert physicians to evaluate each case individually. *Level II, III, IV Evidence; Grade: C*

Risk Factors for Post-operative Complications with Expander/Implants

Smoking

Recommendation: Smoking is associated with an increased risk of complications and an increased risk of reconstructive failure in patients undergoing post-mastectomy expander/implant breast reconstruction. Patients should be informed of the increased risks and advised on smoking

cessation as means to decrease surgical complications. Additionally, it should be recognized that the decision to proceed with surgery may preclude timely smoking cessation. *Level II, III, IV Evidence; Grade: A*

Obesity

Recommendation: A body mass index (BMI) of 25 or greater is associated with an increased risk of post-operative complications and reconstructive failure among patients undergoing post-mastectomy expander/implant breast reconstruction. These risks are even higher among patients with a BMI greater than 30. Obese patients should be informed of their increased surgical risks with expander/implant reconstructions and advised on practical weight loss solutions. Additionally, it should be recognized that the decision to proceed with surgery may preclude timely weight management. *Level III, IV Evidence; Grade: A*

Breast Size

Recommendation: Pre-operative breast size, specifically C or larger, may be associated with an increased risk of complication and an increased risk of reconstructive failure in patients undergoing post-mastectomy expander/implant breast reconstruction. However, much of the currently available evidence does not control for BMI, which is associated with both pre-operative breast size and complication rates. Given the limited evidence and contradictory literature, physicians should be aware of this potential complicating factor. *Level III, IV Evidence; Grade: D*

Diabetes

Recommendation: There is no evidence to indicate that diabetes is a significant independent risk factor for the development of either post-operative complications or reconstructive failure in patients undergoing post-mastectomy expander/implant breast reconstruction. However, this information should not deter surgeons from continuing to practice glycemic control in the peri-operative period for breast cancer patients. *Level II, III, IV Evidence; Grade: B*

Radiation Therapy

Overall Recommendation: The optimal timing of radiation is within eight weeks of the mastectomy. Radiation is associated with an increased risk of complications and reconstructive failure among patients undergoing post-mastectomy expander/implant breast reconstruction. Patients should be counseled in regards to these increased risks. *Level II, III, IV Evidence; Grade: B*

Chemotherapy

Recommendation: Pre-operative chemotherapy does not appear to be a significant risk factor for either post-operative complications or implant failure in patients undergoing post-mastectomy expander/implants breast reconstruction. *Level II, III, IV Evidence; Grade: C*

Hormonal Therapy

Recommendation: Hormonal therapy may increase the risk of post-operative complications and reconstruction failure in patients undergoing post-mastectomy expander/implant breast reconstruction. However, inconsistent research findings and a lack of definitive evidence should alert physicians to evaluate each case individually. *Level II, IV Evidence; Grade: D*

Treatment

Antibiotic Prophylaxis

Recommendation: Patients undergoing post-mastectomy expander/implant breast reconstruction should receive a pre-operative dose of an appropriate intravenous (IV) antibiotic initiated 60 minutes or less from the time of incision (within two hours for antibiotics with longer infusion times). Unless a drain is present, antibiotics should be discontinued within 24-hours of the completion of the procedure. If a drain is present, the role of antibiotics is less clear and should be left to physician preference. Of note, documenting a drain in proximity to the implant as a reason for continuation of IV antibiotics beyond the 24-hour post-operative period or switching to post-operative antibiotics within 24-hours of procedure completion is compliant with current Surgical Care Improvement Project (SCIP) guidelines. Presently, there is limited evidence on post-operative antibiotic prophylaxis. Overall, surgeons should adhere to their specific state and hospital guidelines on antibiotic administration. *Grade: D*

Acellular Dermal Matrix (ADM)

Recommendation: Evidence on ADM in post-mastectomy expander/implant breast reconstruction is varied and conflicting. Surgeons should evaluate each clinical case individually and objectively determine the use of ADM. *Level III Evidence; Grade: C*

Outcomes

Monitoring for Cancer Recurrence

Recommendation: Clinical examination is sufficient to detect local cancer recurrence in patients undergoing post-mastectomy expander/implant breast reconstruction. Imaging studies are not required as part of routine surveillance. On the basis of clinical suspicion, imaging studies can be used for clinical indications on a case-by-case basis. Diagnostic imaging is indicated if there is any clinical concern for recurrence. *Grade: D*

Effect of Implant-based Reconstruction on Oncologic Outcomes

Recommendation: Post-mastectomy expander/implant breast reconstruction does not adversely affect oncologic outcomes. The need for post-mastectomy radiation therapy is often, but not always, apparent prior to surgery; accordingly, decisions regarding the sequencing of post-mastectomy breast reconstruction and radiation therapy are best made by a multidisciplinary team including the oncologic surgeon, plastic surgeon, medical oncologist and radiation oncologist. *Level: III Evidence; Grade: B*

Definitions:

American Society of Plastic Surgeons (ASPS) Evidence Rating Scales

Evidence Rating Scale for Therapeutic Studies

Level of Evidence	Qualifying Studies
I	High-quality, multi-centered or single-centered, randomized controlled trial with adequate power; or systematic review of these studies
II	Lesser-quality, randomized controlled trial; prospective cohort or comparative study; or systematic review of these studies
III	Retrospective cohort or comparative study; case-control study; or systematic review of these studies
IV	Case series with pre/post test; or only post test
V	Expert opinion developed via consensus process; case report or clinical example; or evidence based on physiology, bench research, or "first principles"

Evidence Rating Scale for Diagnostic Studies

Level of Evidence	Qualifying Studies
I	High-quality, multi-centered or single-centered, cohort study validating a diagnostic test (with "gold" standard as reference) in a series of consecutive patients; or a systematic review of these studies
II	Exploratory cohort study developing diagnostic criteria (with "gold" standard as reference) in a series of consecutive patients; or a systematic review of these studies
III	Diagnostic study in nonconsecutive patients (without consistently applied "gold" standard as reference); or a systematic review of these studies
IV	Case-control study; or any of the above diagnostic studies in the absence of a universally accepted "gold" standard
V	Expert opinion developed via consensus process; case report or clinical example; or evidence based on physiology, bench research, or "first principles"

Evidence Rating Scale for Prognostic/Risk Studies

Level of Evidence	Qualifying Studies
I	High-quality, multi-centered or single-centered, prospective cohort or comparative study with adequate power; or a systematic review of these studies

Level of Evidence	Qualifying Studies
II	Prospective cohort or comparative study; retrospective cohort or comparative study; untreated controls from a randomized controlled trial; or a systematic review of these studies
III	Case-control study; or systematic review of these studies
IV	Case series with pre/post test; or only post test
V	Expert opinion developed via consensus process; case report or clinical example; or evidence based on physiology, bench research, or "first principles"

Scale for Grading Recommendations

Grade	Description	Qualifying Evidence	Implications for Practice
A	Strong Recommendation	Level I evidence or consistent findings from multiple studies of Levels II, III, or IV	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
B	Recommendation	Levels II, III, or IV evidence and findings are generally consistent	Generally, clinicians should follow a recommendation but should remain alert to new information and sensitive to patient preferences.
C	Option	Levels II, III, or IV evidence, but findings are inconsistent	Clinicians should be flexible in their decision-making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role.
D	Option	Level V: Little or no systematic empirical evidence	Clinicians should consider all options in their decision-making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Breast cancer

Guideline Category

Counseling

Evaluation

Management

Risk Assessment

Treatment

Clinical Specialty

Nursing

Oncology

Plastic Surgery

Radiation Oncology

Intended Users

Health Care Providers

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To provide evidence-based guidelines that specifically address the risk factors, treatment, anticipated outcomes, and follow-up of patients undergoing breast reconstruction with expanders/implants for the treatment of cancerous defects

Target Population

Patients undergoing breast reconstruction with expanders/implants for the treatment of cancerous defects

Interventions and Practices Considered

Evaluation

1. Pre-operative referral to a plastic surgeon for patients undergoing mastectomy
2. Consideration of immediate versus delayed reconstruction

Risk Factor Considerations

1. Smoking
2. Obesity
3. Breast size
4. Diabetes
5. Radiation therapy
6. Chemotherapy
7. Hormonal therapy

Note: Collagen vascular disease and previous breast surgery were also considered as risk factors, but the systematic literature search process did not retrieve any studies on these topics that met inclusion criteria.

Treatment/Management

1. Antibiotic prophylaxis
2. Acellular dermal matrix (ADM)
3. Monitoring for cancer recurrence
4. Consideration of effects of implant-based reconstruction on oncologic outcomes

Major Outcomes Considered

- Effectiveness and timeliness of patient education and surgical consideration
- Risk factors associated with surgical outcomes
- Treatment effectiveness
- Complications associated with expander/implant reconstruction
- Physical, psychological and oncological outcomes

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Search and Admission of Evidence

Published studies were sought by using electronic and manual search strategies. The primary search, executed from December 2011 to February 2012, was conducted in PubMed with the following keywords, MEDLINE Medical Subject Headings (indicated as [MeSH]), publication types (indicated as [ptyp]), Boolean operators, and limits:

1. (Mammaplasty[MeSH] AND reconstruction) OR "breast reconstruction"
2. Case reports[ptyp] OR Editorial[ptyp] OR Comment[ptyp] OR Letter[ptyp] OR News[ptyp] OR Newspaper article[ptyp] OR In Vitro[ptyp] OR Legal Cases[ptyp] OR Legislation[ptyp]
3. #1 NOT #2; Limits: English, Humans

Recent studies that may not have been indexed (e.g., publisher-supplied and pre-MEDLINE citations) were sought using a keyword search strategy similar to item 1 above, without MeSH terms or limits on publication type, up through the search cut-off date of December 31, 2011. Supplemental electronic searches were performed in the Cumulative Index to Nursing and Allied Health Literature (CINAHL) and the Cochrane Library. In addition, a manual review of reference lists from the previous two years and studies accepted per the conditions designated for the literature search, supplemented the electronic searches.

Study selection for each clinical question was accomplished through two levels of study screening. Level I screening was performed by a single reviewer and involved a review of the titles and abstracts downloaded from the literature search noted above. At Level II screening, the full article was obtained, and the study was reviewed for fit with inclusion and exclusion criteria as outlined in Appendix B in the original guideline document. The reason for exclusion (e.g., no outcomes of interest) was noted for all articles reviewed at Level II that were ultimately found ineligible for inclusion in the guideline. Work Group Members reviewed the list of excluded articles and the reasons for exclusion to determine whether articles should be excluded or reconsidered for inclusion.

Articles were selected for inclusion if they were relevant to clinical questions about risk factors, treatment options, and post-operative complications and if they were deemed high or moderate quality per the American Society of Plastic Surgeons (ASPS) critical appraisal process. Additional references were included if considered necessary for discussion; however, these references were not critically appraised and are clearly documented in the guideline text. Details of literature search terms and search results are provided in Appendix B in the original guideline document.

Number of Source Documents

The literature search identified a total of 2,749 articles that were subject to Level I screening, for a total of 295 remaining articles. After Level II screening and critical appraisal, the results were narrowed to 178 articles, of which ultimately 62 studies were deemed relevant and of high to moderate quality. These studies were used to develop practice recommendations.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

American Society of Plastic Surgeons (ASPS) Evidence Rating Scales

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III	Case-control study; or systematic review of these studies
IV	Case series with pre/post test; or only post test
V	Expert opinion developed via consensus process; case report or clinical example; or evidence based on physiology, bench

Level of Evidence	research, or "first principles" Qualifying Studies

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

Critical Appraisal of the Literature

The American Society of Plastic Surgeons (ASPS) evidence-based process includes a rigorous critical appraisal process. Each study is appraised by at least two reviewers. If a discrepancy exists between the reviewers, the literature is appraised by a third reviewer, and the level of evidence is determined by consensus. Studies are appraised and assigned levels of evidence according to the ASPS Evidence Rating Scales for therapy, risk, and diagnosis (see the "Rating Scheme for the Strength of the Evidence" field). Checklists appropriate for the clinical question (therapy, prognosis/risk, or diagnosis) and study design (randomized controlled trial, cohort/comparative, case control, etc.) are employed. The checklists used by ASPS are similar to commonly used appraisal tools (e.g., checklists developed by the Critical Appraisal Skills Programme [CASP] and the Centre for Evidence Based Medicine [CEBM]). Evidence ratings are not assigned to studies with inadequately described methods and/or worrisome biases.

Methods Used to Formulate the Recommendations

Expert Consensus

Expert Consensus (Nominal Group Technique)

Description of Methods Used to Formulate the Recommendations

Clinical Question Development

Work Group Members utilized the Nominal Group Technique to reach consensus on the clinical questions to be addressed in the evidence-based guideline. The Nominal Group Technique is ideal for face-to-face meetings and is designed to encourage equal participation in Work Group discussions and project contributions. The Work Group completed five rounds of the consensus process. Before the Introductory Meeting, all Work Group Members submitted 97 potential clinical questions, which were compiled and dispersed at the Introductory Meeting for consideration and discussion. The clinical questions were ranked according to the following criteria to assess for potential impact:

1. Relevance to guideline scope
2. Addresses a gap in care
3. Can be developed into an actionable recommendation
4. Can be developed into an implementable recommendation
5. Is controversial or of significant interest
6. Is important to public health

The Work Group agreed on the following clinical questions to address in this evidence-based guideline, including:

1. In patients undergoing surgical treatment for breast cancer, what is the optimal time to discuss breast reconstruction options?
2. In patients undergoing mastectomy for the treatment of breast cancer, what is the optimal time for implant-based reconstruction (i.e., immediate versus delayed) when radiation treatment is not required?
3. In patients undergoing mastectomy for the treatment of breast cancer, what is the optimal time for implant-based reconstruction (i.e., immediate versus delayed) when radiation treatment is required?
4. In patients undergoing breast reconstruction following mastectomy, what are the risk factors when undergoing immediate implant-based reconstruction?
5. In patients requiring radiation therapy and undergoing immediate breast reconstruction after mastectomy, when is the optimal time for

radiation therapy?

6. In patients undergoing implant-based reconstruction after mastectomy, what is the optimal duration of antibiotic prophylaxis for prevention of postoperative infections?
7. In patients undergoing mastectomy and implant-based breast reconstruction, what are the outcomes associated with utilizing acellular dermal matrix during reconstruction?
8. In patients undergoing mastectomy and implant-based breast reconstruction, what are the screening recommendations to monitor for cancer recurrence?
9. In patients undergoing breast reconstruction following mastectomy, what are the oncologic outcomes associated with undergoing immediate implant-based reconstruction?

The systematic review process yielded relevant evidence for six questions. The questions on radiation therapy were combined based on available evidence. Additionally, three clinical questions were addressed through supplemental research and cumulative work group clinical expertise.

Development of Clinical Practice Recommendations

Recommendations were developed through a consensus process. After a thorough review of the evidence, Guideline Work Group Members jointly drafted statements for each recommendation during conference call meetings and online discussions. After each meeting, members had an opportunity to individually comment and revise the draft recommendations via an email discussion. Guideline Work Group Members participated in several rounds of revisions until unanimous consensus was achieved on each recommendation statement. Each recommendation in this guideline is accompanied by a grade indicating the strength of supporting evidence, taking into account the overall level of evidence and the judgment of the guideline developers.

Rating Scheme for the Strength of the Recommendations

Scale for Grading Recommendations

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D	Option	Level V: Little or no systematic empirical evidence	Clinicians should consider all options in their decision-making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role.

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Peer Reviewer Process

The American Society for Therapeutic Radiology and Oncology (ASTRO) and The National Accreditation Program for Breast Centers (NAPBC) were invited to peer review this guideline. In addition, a total of 30 physicians and surgeons were invited to peer review the guideline. Peer review was also performed by volunteers from the American Society of Plastic Surgeons (ASPS) Healthy Policy, Patient Safety, Coding and Payment Policy, and Quality and Performance Measurement Committees. Peer reviewers were given two weeks to review this guideline using an abbreviated version of the Appraisal of Guidelines Research & Evaluation Instrument developed by the AGREE Collaboration.

Guideline Approval Process

After the peer review process, the guideline draft was reviewed and modified by the Post-Mastectomy Expander/Implant Breast Reconstruction Guideline Work Group to address peer review comments. The final guideline was approved by the ASPS Executive Committee during its March 2013 meeting.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate assessment of risk factors, treatment, anticipated outcomes, and follow-up of patients undergoing breast reconstruction with expanders/implants for the treatment of cancerous defects

Potential Harms

Complications associated with expander/implant breast reconstruction most commonly include the following: infection, hematoma, seroma, wound dehiscence, skin flap necrosis, expander/implant loss, malposition, expander/implant deflation, capsular contracture, hypertrophic or keloid scaring, and venous thromboembolism disease.

Qualifying Statements

Qualifying Statements

- Evidence-based guidelines are strategies for patient management, developed to assist physicians in clinical decision making. This guideline was developed through a comprehensive review of the scientific literature and consideration of relevant clinical experience, and describes a range of generally acceptable approaches to diagnosis, management, or prevention of specific diseases or conditions. This guideline attempts to define principles of practice that should generally meet the needs of most patients in most circumstances.
- This guideline should not be construed as a rule, nor should it be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed at obtaining the appropriate results. It is anticipated that it will be necessary to approach some patients' needs in different ways. The ultimate judgment regarding the care of a particular patient must be made by the physician in light of all the circumstances presented by the patient, the available diagnostic and treatment options, and available resources.
- This guideline is not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all the facts or circumstances involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve. This guideline reflects the state of current knowledge at the time of publication. Given the inevitable changes in the

state of scientific information and technology, this guideline will be reviewed, updated and revised periodically.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Patient Resources

Quick Reference Guides/Physician Guides

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

American Society of Plastic Surgeons. Evidence-based clinical practice guideline: breast reconstruction with expanders and implants. Arlington Heights (IL): American Society of Plastic Surgeons; 2013 Mar. 23 p. [71 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2013 Mar

Guideline Developer(s)

American Society of Plastic Surgeons - Medical Specialty Society

Source(s) of Funding

American Society of Plastic Surgeons

Guideline Committee

Post-Mastectomy Expander/Implant Breast Reconstruction Guideline Work Group

Composition of Group That Authored the Guideline

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Financial Disclosures/Conflicts of Interest

All contributors and preparers of the guideline, including American Society of Plastic Surgeons (ASPS) staff and consultants, disclosed all relevant conflicts of interest via an on-line disclosure reporting database. In accordance with the Institute of Medicine's recommendations for guideline development, members with a conflict of interest represented less than half of the Breast Reconstruction Guideline Work Group.

Loree Kalliainen, MD, Work Group Advisor, has no relevant disclosures; Amy Alderman, MD, Work Group Chair, has no relevant disclosures; Amy Ahuja, MPH has no relevant disclosures; Bob Basu, MD has a Research Support Recipient and Consultant relationship with LifeCell Corporation/KCI; Phillip Blondeel, MD has no relevant disclosures; Robert Buchanan, MD has no relevant disclosures; Hiram Cody, III, MD has no relevant disclosures; Diana Frame, MPH has no relevant disclosures; Nolan Karp, MD has a Research Support Recipient relationship with Allergan; Carol Lee, MD has no relevant disclosures; Valerie Lemaine, MD, MPH, FSCRC has a Grant Recipient relationship with Allergan; Raman Mahabir, MD has no relevant disclosures; Galen Perdikis, MD has no relevant disclosures; Neal Reisman, MD, JD has a Consultant Relationships with Allergan and LifeCell Corporation/KCI; Karie Rosolowski, MPH has no relevant disclosures; Kathryn Ruddy, MD, MPH has no relevant disclosures; Mark Schusterman, MD has no relevant disclosures; DeLaine Schmitz, RN, MSHL has no relevant disclosures; Jaime Schwartz, MD has no relevant disclosures; Jennifer Swanson, BS, M.Ed. has no relevant disclosures.

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) from the American Society of Plastic Surgeons Web site .

Print copies: Available from the American Society of Plastic Surgeons, 444 East Algonquin Road, Arlington Heights, IL 60005-4664.

Availability of Companion Documents

The following is available:

- Breast reconstruction physician's counseling guide. Breast mammaplasty. Arlington Heights (IL): American Society of Plastic Surgeons. Available from the American Society of Plastic Surgeons Web site .

Patient Resources

The following is available:

- Breast reconstruction. Patient brochure. Arlington Heights (IL): American Society of Plastic Surgeons; 2010. 15 p. Available in Portable Document Format (PDF) from the American Society of Plastic Surgeons (ASPS) Web site .

In addition, a variety of patient resources on breast reconstruction, including a breast cancer patient education video, a breast reconstruction video, a before and after photo gallery, a patient forum, and an overview video, are available from the ASPS Web site .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

This NGC summary was completed by ECRI Institute on July 29, 2013. The information was verified by the guideline developer on August 29, 2013.

Copyright Statement

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